K974423

STERLING®
Diagnostic Imaging

DEC 22 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUBMITTED BY:
Jean E. Bartlett
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Regulatory Affairs and Quality Assurance
STERLING DIAGNOSTIC IMAGING, INC.
PO Box 19048, Mail Drop 102
Greenville, SC 29602-9048
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DEVICE NAME:
Ultra-Vision® Mammography Detail
Ultra-Vision® Mammography Fast Detail

PREDICATE DEVICE:
Microvision™ Detail

DEVICE DESCRIPTION AND INTENDED USE:
Ultra-Vision® Mammography Detail and Ultra-Vision® Mammography Fast Detail are ultraviolet/blue light emitting, high definition radiographic intensifying screens. The phosphor is niobium activated lutetium tantalate.

These screens are intended for use in radiographic procedures requiring high levels of image quality such as mammography.

DEVICE COMPARISON TO PREDICATE DEVICE:
The Ultra-Vision®Mammography Detail and Ultra-Vision® Mammography Fast Detail are substantially equivalent to the Microvision™ Detail as summarized below:

SUMMARY OF PRODUCT SIMILARITIES/DIFFERENCES

	Ultra-Vision®Mammography Detail	Ultra-Vision®Mammography Fast Detail	Microvision Detail
Phosphor	Lutetium Tantalate	Lutetium Tantalate	Gadolinium Oxysulfide
Speed	1.17	1.53	1.0
MTF @ 4cycles/mm	.675	.635	.635
X-ray Absorption @ 25 kVp	.61	.83	.60
Imaging Application	High Image quality	High Image quality	Mammography

Signature: Jean E Bartlett

Date: 11-19-97

Sterling Diagnostic Imaging, Inc.
10 South Academy Street
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Greenville, SC 29602-9048

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

JeanE Bartlett
Regulatory Affairs &
Compliance Manager
Sterling Diagnostic Imaging, Inc.
10 South Academy Street
P.O. Box 19048
Greenville, SC 29602-9048

Re: K974423
Ultra-vision® Mammography Detail
Ultra-vision® Mammography Fast Detail
Dated: November 21, 1997
Received: November 24, 1997
Regulatory Class: I, Tier II
21 CFR 892.1960/Procode: 90 EAM

Dear Ms. Bartlett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS STATEMENT

510(k) Number (if known): _____

Device Name: Ultra-Vision® Mammography Detail
Ultra-Vision® Mammography Fast Detail

Indications for Use:

These radiographic intensifying screens have application whenever a high image quality radiographic examination such as mammography is required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974423